January 6, 2015

CBIC Control Number 363253_S

Via Federal Express

Document Processing Center (Mail Code 7407M)
Room 6428
Attention: 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
1201 Constitution Ave., NW
Washington, DC 20004

Dear 8(e) Coordinator:

Generic Name: [(substituted heteromonocyclyl)oxycarbomonocyclyl]- (disubstitutedalkyl)heteromonocycle

This letter is to inform you of the results of a developmental toxicity study with the above referenced test substance. The test substance is an R&D substance and to the best of our knowledge not on the public inventory.

Groups of 8 time-mated Crl:CD®(SD) rats were administered formulations of the test substance in 0.5% methylcellulose with 0.1% Tween 80 by once daily gavage on gestation days (GD) 6-20 at daily dose levels of 0, 25, 100 or 500 mg/kg/day. The dose volume was 10 ml/kg for all groups. During the in-life portion of the study, maternal clinical observations, body weights, and food consumption data were collected. On GD 21, all dams were euthanized and a gross external and visceral examination was performed. The uterus of each pregnant female was removed and the uterine contents were examined and described; all fetuses were removed and individually identified, weighed, sexed, and examined for external, visceral, and skeletal alterations. At 500 mg/kg/day, there were test substance-related effects on body weight and food consumption parameters. Mean maternal body weights were 10-23% lower than control group means throughout the study. Final absolute and adjusted body weights were 21% and 19% lower than control groups, respectively at this level. There were mean maternal body weight losses of 19.2 and 24.3 grams on gestation days 6 to 8 and 8 to 10, respectively at 500 mg/kg/day. The overall absolute body weight gains were 60% lower than control at this level. When this body weight gain was adjusted to subtract the products of conception, these animals lost an average of 13 grams at 500 mg/kg/day compared to a gain of 48 grams for the control group. Correspondingly, mean overall food consumption was 35% lower than control group at this level. At 500 mg/kg/day, there were 2 litters observed with a total litter loss, mean fetal weights were 22% lower than control, and mean number of total resorptions was 3.63 compared to 0.13 for the control group. As a result of this increase in fetal resorptions, the total number of live fetuses/litter was reduced at 500 mg/kg/day compared to control. Litters in the 500 mg/kg/day group had an average of 8.3 live fetuses compared to 11.8 for the control group.

Sincerely,

COMPANY SANITIZED

Substantiating Claims of Confidentiality in Submissions to the TSCA §8(e) Office

Confidential Business Information Substantiation

1. Is your company asserting this confidential business information (CBI) claim on its own behalf? If the answer is no, please provide company name, address and telephone number of entity asserting claim.

   [ ]

2. For what period do you assert your claim(s) of confidentiality? If the claim is to extend until a certain event or point in time, please indicate that event or time period. Explain why such information should remain confidential until such point.

   [

   ]

3. Has the information that you are claiming as confidential been disclosed to any other governmental agency, or to this Agency at any other time? Identify the Agency to which the information was disclosed and provide the date and circumstances of the same. Was the disclosure accompanied by a claim of confidentiality? If yes, attach a copy of said document reflecting the confidentiality agreement.

   [ ]

4. Briefly describe any physical or procedural restrictions within your company relating to the use and storage of the information you are claiming CBI.

   [

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5. If anyone outside your company has access to any of the information claimed CBI, are they restricted by confidentiality agreement(s). If so, explain the content of the agreement(s).

   [

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6. Does the information claimed as confidential appear or is it referred to in any of the following:

a. Advertising or promotional material for the chemical substance or the resulting and product;[ ]

b. Material safety data sheets or other similar materials (such as technical data sheets) for the substance or resulting end product (include copies of this information as it appears when accompanying the substance and/or product at the time of transfer or sale);[ ]

c. Professional or trade publications; or
[ ]

d. Any other media or publications available to the public or to your competitors.
[ ]

If you answered yes to any of the above, indicate where the information appears, include copies, and explain why it should nonetheless be treated as confidential.

7. Has EPA, another federal agency, or court made any confidentiality determination regarding information associated with this substance? If so, provide copies of such determinations.

[ ]

8. Describe the substantial harmful effects that would result to your competitive position if the CBI information is made available to the public? In your answer, explain the causal relationship between disclosure and any resulting substantial harmful effects. Consider in your answer such constraints as capital and marketing cost, specialized technical expertise, or unusual processes and your competitor's access to your customers. Address each piece of information claimed CBI separately.

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9. Has the substance been patented in the U.S. or elsewhere? Is a patent for the substance currently pending?

[

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10. Is this substance/product commercially available and if so, for how long has it been available on the commercial market? [ ]

a. If on the commercial market, are your competitors aware that the substance is commercially available in the U.S.?

[ ]

b. If not already commercially available, describe what stage of research and development (R&D) the substance is in, and estimate how soon a market will be established.

[
]

c. What is the substance used for and what type of product(s) does it appear in.

[ ]

11. Describe whether a competitor could employ reverse engineering to identically recreate the substance?

[

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12. Do you assert that disclosure of this information you are claiming CBI would reveal:

a. confidential processes used in manufacturing the substance; [ ]

b. if a mixture, the actual portions of the substance in the mixture; [ ]

c. information unrelated to the effects of the substance on human health or the environment?[ ]

If your answer to any of the above questions is yes, explain how such information would be revealed.

13. Provide the Chemical Abstract Service Registry Number for the product, if known. Is your company applying for a CAS number now or in the near future? If you have applied for a CAS number, include a copy of the contract with CAS.

[ ]

14. Is the substance or any information claimed CBI the subject of FIFRA regulation or reporting? If so, explain.

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